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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/863,824
Filing Date	05/23/01
First Named Inventor	Turner
Group Art Unit	1652
Examiner Name	D. M. Ramirez
Total Number of Pages in This Submission: 18	Attorney Docket Number: LEX-0181-USA

ENCLOSURES *(check all that apply)*

☐ Fee Transmittal Form	☐ Assignment Papers *(for an Application)*	☐ After Allowance Communication to Group
☐ Fee Attached	☐ Drawing(s)	☐ Appeal Communication to Board of Appeals and Interferences
☐ Amendment / Reply	☐ Licensing-related Papers	☒ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
☐ After Final	☐ Petition	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Petition to Convert to a Provisional Application	☐ Status Letter
☐ Extension of Time Request (Original & Copy)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Other Enclosure(s) *(please identify below):*
☐ Express Abandonment Request	☐ Terminal Disclaimer	- Return postcard
☐ Information Disclosure Statement	☐ Request for Refund	
☐ Certified Copy of Priority Document(s)	☐ CD, Number of CD(s) _____	
☐ Response to Missing Parts/ Incomplete Application	Remarks	**FILED IN TRIPLICATE**
☐ Response to Missing Parts under 37 CFR 1.52 or 1.53		**Customer # 24231**

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Lexicon Genetics Incorporated Lance K. Ishimoto Reg. No. 41,866
Signature	Per Lance Ishimoto by Peterka Setarian Reg. No. 40162
Date	January 20, 2004

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as Express mail label EV232149587US addressed to: Commissioner for Patents, MS Appeal Brief - Patents, P.O. Box 1450, Alexandria, VA 22313 on: January 20, 2004

Typed or printed name	Nancy Stacey		
Signature	Nancy Stacey	Date	January 20, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Turner *et al.*		
Serial No.:	09/863,824	Group Art Unit:	1652
Filed:	5/23/01	Examiner:	D. M. Ramirez
For:	Novel Human Thrombospondin-Like Proteins and Polynucleotides Encoding the Same	Attorney Docket No.:	LEX-0181-USA

REPLY BRIEF

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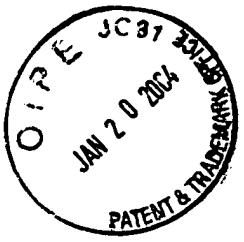

REPLY BRIEF

Sir:

Appellants hereby submit an original and two copies of this Reply Brief to the Board of Patent Appeals and Interferences ("the Board") in response to the Examiner's Answer mailed on November 17, 2003 which is due on Saturday, January 17, 2004, which is on a weekend and is followed by a Federal holiday and is therefore extended until Tuesday, January 20, 2004 under 37 CFR § 1.7. This Reply Brief is thus timely submitted.

Appellants believe no additional fees are due in connection with this Reply Brief. However, should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason related to this communication, the Commissioner is authorized to charge any underpayment or credit any overpayment to Lexicon Genetics Incorporated Deposit Account No. 50-0892.

I. REAL PARTY IN INTEREST

Appellants agree with the Examiner's assertion that "A statement identifying the real party in interest is contained in the brief" (Examiner's Answer at page 1).

II. RELATED APPEALS AND INTERFERENCES

Appellants agree with the Examiner's assertion that "Appellant's brief includes a statement that there are no related appeals and interferences" (Examiner's Answer at page 1).

III. STATUS OF THE CLAIMS

Appellants agree with the Examiner's assertion that "The statement of the status of the claims contained in the brief is incorrect" (Examiner's Answer at page 2), as it contains a clerical error. As correctly noted in the Examiner's Answer, the Advisory Action (mailed on June 3, 2003) maintained the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 101 as allegedly lacking a patentable utility, and

the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 112, first paragraph, however the rejection of Claim 2 under 35 U.S.C. § 112, second paragraph was overcome by amendment in Appellants' Response, mailed on May 5, 2003 and this was clearly indicated in the Advisory Action as noted.

IV. STATUS OF THE AMENDMENTS

Appellants agree with the Examiner's assertion that "The statement of the status of the amendments after final rejection contained in the brief is incorrect" (Examiner's Answer at page 2), as it contains a clerical error. As correctly noted in the Examiner's Answer, the Advisory Action (mailed on June 3, 2003) maintained the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 101 as allegedly lacking a patentable utility, and the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 112, first paragraph, however the rejection of Claim 2 under 35 U.S.C. § 112, second paragraph was overcome by amendment in Appellants' Response, mailed on May 5, 2003 and this was clearly indicated in the Advisory Action as noted. Appellants' also note that an amendment to the Abstract was not submitted, this error was the result of a clerical error.

V. SUMMARY OF THE INVENTION

Appellants essentially agree with the Examiner's assertion that "The summary of invention contained in the brief is essentially correct." (Examiner's Answer at page 2).

VI. ISSUES ON APPEAL

Appellants agree with the Examiner's assertion that "The Appellant's statement of the issues in the brief is correct" and with Examiner's notation regarding Claim 2 and, as correctly noted in the Examiner's Answer, the Advisory Action (mailed on June 3, 2003) maintained the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 101 as allegedly lacking a patentable utility, and the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 112, first paragraph, however the rejection of Claim 2 under

35 U.S.C. § 112, second paragraph was overcome by amendment in Appellants' Response, mailed on May 5, 2003 and this was clearly indicated in the Advisory Action as noted. Appellants' also note that an amendment to the Abstract was not submitted, this error was the result of a clerical error.

VII. GROUPING OF THE CLAIMS

Appellants agree with the Examiner's assertion that "Appellant's brief includes a statement that the claims will stand or fall together" (Examiner's Answer at page 3).

VIII. CLAIMS APPEALED

Appellants agree with the Examiner's assertion that "(t)he copy of the appealed claims contained in the Appendix to the brief is correct" (Examiner's Answer at page 3).

IX. PRIOR ART OF RECORD

Appellants agree completely with the Examiner's assertion as to the art previously presented by the Examiner in this case (Examiner's Answer at page 3).

X. ARGUMENT

A. Do Claims 2, 3, 6 and 7 Lack a Patentable Utility?

Appellants do not wish to restate all of the arguments presented in the Appeal Brief concerning the Examiner's allegation that claims 2, 3, 6 and 7 lack a patentable utility, and instead incorporate the entirety of Section VIII(A) of the Appeal Brief at this point herein by reference. However, Appellants feel the need to specifically address several of the arguments presented in the Examiner's Answer in some detail for the record.

In the Examiner's Answer the position that the argument that the polymorphisms described in the specification have patentable utility is deemed to be nonpersuasive. This is because the asserted utilities

of the present nucleic acid sequences in forensic analysis, human population biology, or paternity identification are not specific or substantial.

On page 11, line 6 of the Examiner's Answer the Examiner acknowledges that Appellants had identified 3 polymorphisms in the Appeal Brief however on line 19 of page 11 of the Examiners Answer, the Examiner acknowledges only two polymorphisms in the specification. For the record Appellants reiterate that the specification at page 16, line 21-31 identified the following polymorphisms. The A-G transition that can occur at nucleotide position number 364, of SEQ ID NO:1 and the A-or-T transversion that can occur at nucleotide position number 365 of SEQ ID NO:1 that can give rise to either a asparagine or valine at corresponding amino acid position 122 of SEQ ID NO:2, and an A-or-G transition polymorphism at nucleotide position 535 of, for example, SEQ ID NO:1 which can give rise to a lysine or a glutamic at corresponding amino acid position 179 of, for example, SEQ ID NO:2. These three polymorphisms provide significant and specific utility as taught in the specification.

Naturally occurring genetic polymorphisms are both the basis of, and critical to, *inter alia*, forensic genetic analysis and genetic analysis intended to resolve issues of paternity. Throw away utilities? Appellants find this position difficult to comprehend, given that the results of paternal analysis often have great emotional and substantial economic impact. This does not sound like a throw away utility, rather it sounds like a very substantial and real world utility. What could be more substantial and real world than the loss of an individual's freedom through incarceration and in some cases even the loss of life through execution? Yet forensic analysis based on identified polymorphisms is often used to convict or acquit in many cases. Both paternal and forensic genetic analysis is based on identified polymorphisms. This is a well known and generally accepted by those of skill in the art, who would readily recognize the utility and value of any identified polymorphism. Without identified polymorphisms, one would not be able to carry out such forensic or paternal analyses. The present application has identified such polymorphisms in the sequences of the present invention.

As such polymorphisms are the basis for forensic analysis, paternity identification and population biology studies, which are undoubtedly "real world" utilities, the present sequences must in themselves be useful. In and of themselves each of these polymorphisms, including the silent ones, has significant and

specific utility, the specificity of this utility is only amplified by the presence of so many polymorphisms that can arise in various combinations. It is also important to note that the presence of more useful polymorphic markers for such analysis would not mean that the present sequences lack utility.

Appellants respectfully point out that those of skill in the art would readily recognize that the presently described polymorphisms, exactly as they were described in the specification as originally filed, are useful in forensic analysis, population biology and paternity analysis to specifically identify individual members of the human population based on the presence or absence of the described polymorphism. Simply because the use of these polymorphic markers will necessarily provide additional information on the percentage of particular subpopulations that contain one or more of these polymorphic markers does not mean that "additional research" is needed in order for these markers as they are presently described in the instant specification to be of use to forensic science. As stated above, using the polymorphic markers as described in the specification as originally field will definitely distinguish members of a population from one another. In the worst case scenario, each of these markers are useful to distinguish 50% of the population (in other words, the marker being present in half of the population). The ability to eliminate 50% of the population from a forensic analysis clearly is a real world, practical utility. Therefore, any allegation that the use of the presently described polymorphic markers is only potentially useful would be completely without merit, and would not support the alleged lack of utility.

In the Examiner's Answer (last paragraph of page 11 through the first paragraph of page 12) as polymorphisms are found in most genes and any polymorphism can be used in forensic analysis or in human paternity determination, such polymorphisms lack substantial and specific utility in the absence of identification of the characteristics of populations bearing such polymorphisms. Appellants respectfully disagree. As stated without further experimentation those of skill in the art would recognize the utility of the identified polymorphisms and how the asserted markers can distinguish 50% of the population in the worst case scenario. Thus the presence or the absence of a particular specific polymorphism is sufficient for use in the proposed utilities. Appellants provide the following detailed explanation. Those of skill in the art would recognize that in the worst case, least useful situation, a marker would be present in half of a population and absent from the other half. Therefore the probability of an individual having such a

marker would be 1 in 2 or 50%. Using the forensic analysis scenario for example, the analysis will have removed 50% of the possible suspects from the list, as either the suspect has the identified polymorphism or not. However, if a polymorphism were present in only say 10% of the population, the probability of an individual having such a polymorphic marker would be 1 in 10 (10%) and 90% of suspects could be eliminated from investigation or prosecution based on the presence or absence of the polymorphism. Clearly eliminating 90% of the suspects is better than eliminating 50% of the suspects. That said, eliminating half of the suspects on a list is without question very useful to any investigator.

It should be noted that because the specification identified multiple polymorphisms that could be present a different locations within the sequences of the present invention, the identified polymorphisms are particularly useful due to the ability to combine the presence or absence of a marker at each site to enhance the ability of these sequences to distinguish individuals from within a population.

Until a polymorphic marker is actually described it has very limited utility in forensic analysis. Put another way, simply because there is a likelihood, even a significant likelihood, that a particular nucleic acid sequence will contain a polymorphism and thus be useful in forensic analysis, until such a polymorphism is actually identified and described, such a likelihood is **meaningless**. The Examiner appears to be attempting to use the information presented for the first time by Appellants in the instant specification as hindsight verification that the presently claimed sequence would be expected to have polymorphic markers. Such hindsight analysis based on Appellants discovery is completely improper. Second, the Examiner is clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard. The relevant case law cited by Appellants in the Appeal Brief makes it abundantly clear that the presence of other or even more useful polymorphic markers for forensic analysis does **not** mean that the present sequences lack a specific utility. As **clearly** stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a

lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Importantly, the holding in the *Carl Zeiss* case is **mandatory legal authority** that essentially controls the outcome of the present appeal. This case, and particularly the cited quote, **directly** rebuts the Examiner's argument, which is presumably why the Examiner failed to address the holding of *Carl Zeiss* in the Examiner's Answer. Furthermore, the requirement for a unique utility is clearly not the standard adopted by the Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer and bacterial or viral infections, just to name a few particular examples, because examples of each of these have already been described and patented. **All** batteries have the **exact same** utility - specifically, to provide power. **All** automobile tires have the **exact same** utility - specifically, for use on automobiles. **All** golf balls and golf clubs have the **exact same** utility - specifically, use in the game of golf. **All** cancer treatments have the **exact same** utility - specifically, to treat cancer. **All** anti-infectious agents have the **exact same** broader utility - specifically, to treat infections. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Furthermore, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

Appellants respectfully submit that to be used in forensic or paternal genetic analysis a human nucleic acid must contain an identified polymorphism and in fact it is the multiple polymorphisms described in the specification that would provide just such a group of "specific features", should they have been needed. The presently described **polymorphisms** are part of the **family of polymorphisms** that have a well established utility and Appellants reliance on *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*") is not at all misplaced.

The present specification identified a transcribed and spliced and gene that encodes a novel human

thrombospondin-like protein expressed in human brain, fetal brain, pituitary, cerebellum, spinal cord, thymus, spleen, trachea, kidney, liver, thyroid, adrenal gland, salivary gland, heart, uterus, stomach, small intestine, placenta, mammary gland, adipose, skin, esophagus, cervix, pericardium and fetal lung tissue but not in the other human tissues examined.

However the Examiner's position is that the art teaches that it is impossible to predict precisely the functions protein molecules solely base upon sequence analysis. In the Advisory Action, however, reiterates the Examiner's position that structural homology is not sufficient to assign function and provides additional citations to support of this position. The Examiner had previously cited Bork (Genome Research *10*:398-400, 2000) as supporting the proposition that prediction of protein function from homology information is somewhat unpredictable and had directed attention to page 399, on which the author notes the limitations of various methods of analysis. It is of interest that in his "analysis" Bork often uses citations to many of his own previous publications, an interesting approach. ' My position is supported by my previous disclosures of my position.' If Bork's position is supported by others of skill in the art, one would expect that he would reference them rather than himself to provide support for his statements. Given that the standard with regard to obtaining U.S. patents is those of skill in the art, this observation casts doubt on the broad applicability of Bork's position. It should also be noted that in Table 1, on page 399, in which selected examples of prediction accuracy are presented, that the reported accuracy of the methods which Appellants have employed are, in fact, very high. While nowhere in Bork is there a comparison of the prediction accuracy based on the percentage homology between two proteins or two classes of proteins, " Homology (several methods)" is assigned an accuracy rate of 98% and "Functional features by homology" is assigned an accuracy rate of 90%. Given that these figures were obtained based on what is at least a 4 year old analysis, these high levels of accuracy would appear to support rather than refute Appellants' assertions in the present case. Additionally Bork even states (on page 400, second column, line 17) that " However, there is still no doubt that sequence analysis is extremely powerful". In summary, it is clear that it is not Bork's intention to refute the value of sequence analysis but rather he is indicating that there is room for improvement.

The Examiner also cites Broun *et al.* (Science *282*:1315-1317, 1998) and Van de Loo *et al.*

(Proc. Natl. Acad. Sci. USA *92*:6743-6747, 1995) as teaching that prediction of function based on homology is unpredictable. However, these papers each cite only one example, microsomal oleate desaturase/oleate 12-hydroxylase, where function based on sequence homology proved to be incorrect. Also cited are Witkowski *et al.*, (Biochemisty 38:11643-11650, 1999), as allegedly teaching how an amino acid substitution eliminates β-ketoacyl synthase activity and Seffernick, *et al.*, (J. Bact. 2001, *183*:2405-2410) as teaching that prediction of function based on homology is unpredictable. However, this paper describes only one example, comparing Melamine Deaminase and Atrazine Chlorohydrolase (neither of which are thrombospondins) where function based on sequence homology proved to be incorrect. These references represent a few select examples out of the thousands of predictions of function based on homology that exist in the art is hardly indicative of a high level of uncertainty, and thus also does not support the alleged lack of utility. In the present case, the Examiner has taken what has become a common approach by citing the occasional journal article to support an allegation of a lack of utility, the PTO has repeatedly attempted to deny the utility of nucleic acid sequences based on a small number of publications that call into doubt prediction of protein function from homology information and the usefulness of bioinformatic predictions, of which these articles are merely the latest examples. Appellants agree that there is not 100% consensus within the scientific community regarding prediction of protein function from homology information, and further agree that prediction of protein function from homology information is not 100% accurate. However, Appellants respectfully point out that the lack of 100% consensus on prediction of protein function from homology information is irrelevant to the question of whether the claimed nucleic acid sequence has a substantial and specific utility, and that 100% accuracy of prediction of protein function from homology information is **not the standard** for patentability under 35 U.S.C. § 101. Appellants respectfully point out that, as discussed above, the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be **believable**. Appellants submit that the overwhelming majority of those of skill in the relevant art would **believe** prediction of protein function from homology information and the usefulness of bioinformatic predictions to be powerful and useful tools, as evidenced by extensive number of journal articles (which support Appellants' assertion that the overwhelming majority of those of skill in the art place a high value

on prediction of protein function from homology information and the usefulness of bioinformatic predictions), and would thus **believe** that Appellants' sequence is a thrombospondin like protein. As **believability** is the standard for meeting the utility requirement of 35 U.S.C. § 101, and **not** 100% consensus or 100% accuracy, Appellants submit that the present claims must clearly meet the requirements of 35 U.S.C. § 101.

In summary, it is clear that it is not Bork's intention in this or in the other articles frequently cited by Examiners to refute the value of sequence analysis but rather he is indicating that there is room for improvement. All of the issues raised in these articles can effect the accuracy of sequence base analysis, however, can all be overcome by a more careful analysis as would be done by one of skill in the art. Automatic methods of sequence homology as identified by any algorithm are a staring point for consideration, and one of skill in the art can then through further analysis, structure - function analysis, etc., can and should then verify the associations. For example in addition to algorithm based sequence analysis the sequences of the present invention underwent careful analysis by a series of individuals of skill in the art, many highly qualified (B.S. and multiple Ph.D. level scientists). Clearly such highly skilled and careful analysis reduces the influence of such issues.

Given the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable, this is clear evidence that those skilled in the art would have recognized the function and activity of the protein encoded by the sequences of the present invention, there can, therefore, be no question that Appellants' asserted utility for the described sequences is "credible." According to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on lack of utility (66 Federal Register 1098, January 5, 2001).

Appellants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657

(Bd. Pat. App. & Inter. 1988)), and thus the question of the utility of the presently claimed invention should be laid to rest. However, Appellants pointed to a number of additional utilities of the present sequence, including use in a gene chip format to provide a high throughput analysis of the level of gene expression, in determining the genomic structure of the genetic locus encoding the claimed sequence, by defining how the encoded exons are actually spliced together to produce an active transcript, and in mapping the claimed sequence to the corresponding region of the human chromosome on which these exons are encoded.

The Examiner's main argument concerning these utilities is that other nucleic acid sequences can be used in a similar fashion. In addition to the detailed arguments presented by Appellants in the Appeal Brief with regard to each of these asserted utilities, Appellants once again point out that these arguments are completely rebuffed by the Federal Circuit's holding in *Carl Zeiss, supra* ("[A]n invention need not be the best or only way to accomplish a certain result"). As the main argument concerning this utility and that of use of the specific sequences on DNA chips (presented below) is that since other nucleic acid sequences can be used to map the human chromosome or on DNA chips, these do not represent specific or substantial utilities. However, as previously presented, don't all golf balls and tires have the same utility of other golf balls or tires, i.e. they can be used as golf balls or tires respectively and yet these items are readily considered to have patentable utility.

Furthermore, it has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974; "*Langer*"); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). As clearly set forth in *Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Appellants respectfully point out that knowledge of the exact function or role of the presently claimed sequence is not required to track expression patterns using a DNA chip. Given the widespread utility of such "gene chip" methods using *public domain* gene sequence information, there can be little doubt that the use of the presently described *novel* sequences would have great utility in such DNA chip applications. In fact some such gene chips have contained randomly generated sequence.

However, in contrast the sequences of the present invention provide a specific marker of the gene that is transcribed, spliced and encodes a novel human transporter that is expressed in some human tissues and not others. Thus, these sequences provide a unique identifier of the corresponding gene in the human genome. Thus, those skilled in the art would instantly recognize that the present nucleotide sequence would be an ideal, novel candidate for assessing gene expression using, for example, DNA chips, as the specification details. The Examiner agrees that such "DNA chips" have utility, as evidenced by hundreds of issued U.S. Patents, but argues that specific sequences which clearly increase the utility of a patented invention do not. It must be noted that this position runs counter to that made by the Examiner regarding golf balls, wherein the presence of a specific feature that enhances the utility of the golf ball has utility.

For each of the foregoing reasons, as well as the reasons set forth in the Appeal Brief, Appellants submit that the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 101 must be overruled.

B. Are Claims 2, 3, 6 and 7 **Unusable Due to a Lack of Patentable Utility?**

Regarding the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by either a clear asserted utility or a well-established utility, Appellants submit that as claims 2, 3, 6 and 7 have been shown to have "a specific, substantial, and credible utility", as detailed in Section X(A) above, as well as Section VIII(A) of the Appeal Brief, the present rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 112, first paragraph, cannot stand.

Appellants therefore submit that the rejection of claims 2, 3, 6 and 7 under 35 U.S.C. § 112, first

paragraph, must be overruled.

XI. CONCLUSION

Appellants respectfully submit that, in light of the foregoing arguments, the Final Action's conclusion that claims 2, 3, 6 and 7 lack a patentable utility and are unusable by the skilled artisan due to a lack of patentable utility is unwarranted. It is therefore requested that the Board overturn the Final Action's rejections.

Respectfully submitted,

January 20, 2004
Date

Lance K. Ishimoto Reg. No. 41,866
Agent For Appellants

LEXICON GENETICS INCORPORATED
(281) 863-3110

Customer # 24231